

REMARKS

The applicants acknowledge the Office Action of March 22, 2007 with appreciation. The Examiner acknowledges the cancellation of Claims 1-20 with the Preliminary Amendment of January 31, 2006, and indicates that Claims 21-28 are pending and are presently under examination. The status of Claims 29-40 is not indicated in the instant Office Action. The Applicants respectfully request that the Office acknowledge the pendency of all of Claims 21-40 in the instant application.

REJECTION UNDER 35 U.S.C. § 112

The Office rejects Claims 21-26 under 35 U.S.C. § 112, second paragraph, for failing to claim with particularity. The Office concludes that the language, drawn to “anti-apoptotic proteins of the Bcl-2 family” in generic Claim 21 is ambiguous and unclear as to which proteins are encompassed by this term.

To respond to the instant rejection for failing to claim with particularity, the Applicants submit that the language which recites “anti-apoptotic proteins of the Bcl-2 family” is defined at page 2, lines 12-15 of the instant Specification. Moreover, the Applicants submit that anti-apoptotic proteins of the Bcl-2 family are well-known to those skilled in the art, which understanding is supported by extensive literature in the form of review articles and books which describe the general knowledge in the field of Bcl-2 proteins. With the instant Response, the Applicants supply the reference Cory, et al., which reference disclosure is representative of the understanding of those skilled in the art with regard to the term “anti-apoptotic members of the Bcl-2 family”, which describes such proteins (see page 648). In view of the foregoing, the Applicants submit that the claim language drawn to “anti-apoptotic members of the Bcl-2 family” finds support in the instant Specification which defines such proteins, and which claim language is consistent with the understanding of those skilled in the art. Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

Furthermore, the Office concludes that the term "point mutant" in Claim 23 is confusing because it is not known whether the term is referring to a single point mutant or multiple point mutants of SEQ ID NO:1.

In response, the Applicants submit that support for claims to "point mutants" may be found in the instant Specification at page 4, lines 1-3. According to the Specification description, a point mutant is a functional variant of the peptide defined in SEQ ID NO:1. The Applicants submit that one skilled in the art understands that variants may be obtained by modifications such as additions, mutations, deletions and/or substitutions of nucleotides coding for the considered amino acid sequences. These modifications may be undertaken using conventional methods known in the art such as site-directed mutagenesis. These alternatives or modifications may generate different functional variants. More specifically, the instant Specification describes a functional variant to be any modified sequence conserving the properties of SEQ ID NO:1 for interaction with anti-apoptotic proteins of the Bcl-2 family.

The Applicants submit that Example 1 of the instant Specification, at pages 7-9, provides one skilled in the art with guidance for evaluating the interaction of peptides with anti-apoptotic proteins of the Bcl-2 family. Moreover, the Applicants submit that such a two-hybrid method for determining protein-protein interactions is well-known to those skilled in the art, and that a person skilled in the art may easily test modified variants and identify which one has the capacity to bind an anti-apoptotic protein of the Bcl-2 family. The term "point mutant" is described to be a functional variant of SEQ ID NO:1, which description provides a structural/functional basis for one skilled in the art to comprehend the claimed genus.

The Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

REJECTION UNDER 35 U.S.C. § 102(b)

Moving on, Claims 21-22, 24-25 and 27-28 are rejected under 35 U.S.C. §102(b) as being anticipated by the disclosure of Shimkets, et al., International Application Publication Number WO/2000/058473 and Geneseq Database (Accession No. AAC74541, 2/2001).

Shimkets, et al. disclose polynucleotides encoding ORFX and antibodies that immunospecifically bind to ORFX. The Office concludes that Shimkets, et al. disclose an isolated polypeptide comprising SEQ ID NO:1, which relationship is depicted in the amino acid sequence alignment of SEQ ID NO:1 with nucleotides 715-780 of Shimkets, et al. The Office concludes that Shimkets, et al. anticipate the instant claims.

Presumably, the Office is applying the inherency doctrine to conclude that the amino acid sequence as presently claimed is inherent in the protein described by Shimkets, et al. However, the Applicants submit that to maintain a novelty rejection based on inherency, recognition of the claimed subject matter by one skilled in the art must be available from the disclosure of the reference.

Curiously, the Office is applying the doctrine of inherency, misinterpreting the teaching that, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element "is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *In re Cont'l Can Co. v. Monsanto Co.*, 948 F2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

The Applicants submit that one skilled in the art could not envision the isolated peptide having the amino acid sequence as presently claimed, from the broader amino acid sequence of Shimkets, et al. The identification of this particular interaction domain, which allows the formation of homo- and hetero-dimers, is not disclosed in Shimkets, et al., nor is a procedure to identify such domain. Moreover, it may not be inferred that the deduced amino acid sequence of Shimkets, et al.

would function as the isolated species of the instant invention. Consequently, the Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) over Shimkets, et al.

The Office rejects Claims 23 and 26 under 35 U.S.C. § 102(b) over the disclosure of Hammond, et al. (U.S. Application Publication No. 2003/0032157). The Office concludes that Hammond, et al. teach a point mutant of SEQ ID NO:1, and therefore, anticipates the claims.

The Applicants submit that Hammond, et al. do not disclose a sequence identical to functional variants, including point mutants, of SEQ ID NO:1 or a functional portion thereof, and consequently do not anticipate the subject matter of Claim 23.

Hammond, et al. do not anticipate an amino acid sequence as in Claim 23 because Hammond, et al. do not disclose an amino acid sequence having the structural and functional features of an interaction domain which forms homo- and hetero-dimers. Consequently, reconsideration and withdrawal of the rejection for anticipation over the Hammond, et al. disclosure is respectfully solicited.

DISCLOSURE UNDER 37 CFR §§ 1.97 AND 1.98:

Herewith, in accord with the foregoing regulations, please find an Information Disclosure Statement and copies of the documents listed thereon.

As will be noted, this Information Disclosure Statement calls a number of prior art references, which might be considered relevant, to the attention of the Office. The fact that these are in fact "Prior Art" and/or relevant to the prosecution is, however, not admitted. In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. It is understood that, during examination, the Office will make an independent search and will identify any relevant prior art under 37 CFR § 1.104(a).

* * * * *

Accordingly, entry of the present response and Information Disclosure Statement, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By:


G. PATRICK SAGE, #37,710

Dated: August 22, 2007
Customer No.: 25,666
Seventh Floor, Kalamazoo Building
107 West Michigan Ave.
Kalamazoo, MI 49007
(269) 382-0030

Enclosure: Extension of time fee, two (2) months, in the form of a check in the amount of \$450.00; Information Disclosure Statement and fee, in the form of a check in the amount of \$180.00, accompanying references and Postal Card Receipt.

* * * * *

THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.